REMARKS

Claims 19, 21, 22 and 24-35 are currently pending. In the Final Office Action mailed February 13, 2006, the Examiner has raised several issues, which are set forth by number in the order they are addressed herein:

1) Claims 19, 21, 22 and 24-35 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly lacking enablement;
2) Claims 19, 24 and 25-35 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement;
3) Claims 19, 24, 25-29 and 33-36 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly lacking enablement; and
4) Claims 19, 24, 25-29, and 33-36 stand rejected under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement.

Applicant has amended Claims 19 and 26, and the title, in order to further the prosecution of the present application and Applicant's business interests, yet without acquiescing to the Examiner's arguments. Applicant reserves the right to prosecute the original, similar, or broader claims in one or more future application(s). The amendments do not introduce new matter.

1) The Claims Are Enabled

The Examiner has rejected Claims 19, 21, 22 and 24-35 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The Examiner states that the "specification appears to be drawn only to the use of the claimed peptides as an anticancer vaccine" and notes that the title recites a universal vaccine. Applicant disagrees with this statement and respectfully draws the Examiner's attention to the Specification, which discloses that "[a]nother object of the invention is a method for inducing and enhancing a CTL response against cancer cells" (Specification, at page 7, lines 18 and 19). Further support for uses of the claimed peptides beyond an anticancer vaccine can be found but is not limited to the legends of Figures 1 and 2 describing the reduction to practice of compositions for "[i]nduction of CTL against hTRT in peripheral blood leukocytes (PBMC) from normal blood donors," and "[i]nduction of CTL against hTRT in PBMC from prostate cancer patients," respectively (Specification, at page 8, lines 10 and 11, and 19 and 20). Support for additional uses of the claimed embodiments can be

found for instance in Examples 2, 3, 5 and 7-11, as well as original Claims 14-18 (now withdrawn). Even so, Applicant has amended the title to recite "A Composition And Method For Inducing And Enhancing A Telomerase Reverse Transcriptase-Reactive Cytotoxic T Lymphocyte Response," in order to further the prosecution of the present application and Applicant's business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Support for the amendment to the title can be found in original Claims 14-16, among other locations, which are directed to methods "for inducing and enhancing a CTL response against cancer cells."

In addition, the Examiner reminds Applicant "that the claims are read in light of the specification," and further contends that demonstrations of in vitro immunization of murine and human PBMCs is not enabling for the reasons of record" (Final Office Action, Section 4, pp. 2-3, and Office Action mailed June 22, 2005, Section 6, pp. 3-6). In reply Applicant respectfully reminds the Examiner that:

> Office personnel should also be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention. ... Doing so can inappropriately change the relationship of an asserted utility to the claimed invention and raise issues not relevant to the examination of that claim (MPEP, 2707.02). [Moreover a]lthough the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant again contends that the Examiner's rejection of the pending claims on the basis that the Specification does not enable a "universal cancer vaccine," is *improper* since the pending claims do not recite the term "vaccine." Additionally, Applicant respectfully reminds the Examiner that when:

> multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention (MPEP, 2164.01(c), emphasis added).

Thus, since multiple uses of the claimed invention are enabled by the Specification as filed, according to Office rules, the application is enabling for the claimed invention. Applicant contends that the Examiner must provide evidence of why the specification fails to enable all disclosed uses of the claimed invention (e.g., induction of a CTL response in mice and humans, in vitro, in vivo, etc.), not simply evidence of why the specification fails to enable one contemplated use of the claimed invention (e.g., anticancer vaccine). Short of this showing, the enablement rejection of the pending claims cannot stand.

2. The Claims Meet the Written Description Requirement

The Examiner has rejected Claims 19, 24 and 25-35 under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement for the reasons previously set forth in the paper mailed June 22, 2005, Section 12, pp. 13-15. The Examiner states:

> Applicant argues that cancellation of claim 8 and amendment of the claim to recite "a human telomerase reverse transcriptase peptide" obviates this rejection. The argument has been considered but has not been found persuasive because the (Final Office Action, Section 5, mis-numbered as a first Section 6, p. 3).

Applicant contends that the instant Final Office Action is improper in that the Examiner has not addressed Applicant's amendments and arguments of record in the Response received November 28, 2005 with the above sentence fragment. Applicant also contends that this rejection of Claims 30-32 is improper in that these claims all refer to the primary amino acid sequences of the recited hTRT peptides (SEQ ID NOs:18, 20, and 22, respectively).

Even so, Applicant makes a good faith effort to rebut this rejection by relying on the prior Office Action, in which the Examiner states:

> the specification does not describe a telomerase reverse transcriptase (TRT) peptide required to practice the method of the pending claims in a manner that satisfies the Lilly standards since it only describes a single human telomerase reverse transcriptase peptide and isolated fragments thereof (Office Action mailed June 22, 2005, p. 14).

Although Applicant respectfully disagrees that the pending claims fail to meet the written description requirement, Applicant has amended Claims 19 and 26, in order to further the

prosecution of the present application and Applicant's business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). In particular, Applicant has amended Claims 19 and 26 to recite a "human telomerase reverse transcriptase (TRT) peptide nine amino acid residues in length of a human TRT protein consisting of a sequence set forth in SEQ ID NO:23." Support for this amendment can be found for instance in Figure 5, and Nakamura et al., Science, 277:955-959, 1997, cited in the figure legend and incorporated by reference (See, Specification, at page 1, lines 12-14). Thus, the amended claims now recite the human telomerase reverse transcriptase protein and isolated fragments thereof that the Examiner admits are described in the application as filed. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

3) The Claims Are Enabled

The Examiner as rejected Claims 19, 24, 25-29 and 33-36 under 35 U.S.C. § 112 first paragraph, as allegedly lacking enablement. In particular, the Examiner states that:

> the specification while being enabling for peptides consisting of nine amino acids, does not reasonably provide enablement for peptides consisting of from seven to fifteen amino acid (Final Office Action, Section 6, pp. 3 and 4).

Although Applicant respectfully disagrees that the claims lack enablement for hTRT peptides that are shorter or longer than nine amino acids, as discussed above in Section 2, Applicant has amended Claims 19 and 26 to recite a "human telomerase reverse transcriptase (TRT) peptide nine amino acid residues in length." Support for this amendment is found in various locations in the application as originally filed including the summary which teaches that preferably "the peptide is from about 7 to about 15 amino acid residues in length, and most preferably, a 9mer" (Specification, at page 7, lines 11 and 12). Thus, Applicant contends that the amended claims are enabled and respectfully requests that this rejection be withdrawn.

4) The Claims Meet the Written Description Requirement

The Examiner has rejected Claims 19, 24, 25-29, and 33-36 under 35 U.S.C. § 112 first paragraph, as allegedly failing to meet the written description requirement. In particular, the

Examiner contends that support is lacking for HLA-A2.1-restricted, human TRT peptides from seven to fifteen residues in length (Final Office Action, Section 7, pp. 4 and 5). Although Applicant respectfully disagrees that the claims lack enablement for HLA-A2.1-restricted hTRT peptides that are shorter or longer than nine amino acids, as discussed above in Sections 2 and 3, Applicant has amended Claims 19 and 26 to recite a "human telomerase reverse transcriptase (TRT) peptide nine amino acid residues in length." Support for this amendment is found in various locations in the application as originally filed including the Examples 10 and 11, and Tables II, IV and VI, which teach exemplary HLA-A2.1-restricted hTRT nonamers. Therefore, Applicant contends that the amended claims are enabled and respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicant believes the amendments and arguments set forth above traverse the Examiner's rejections and therefore request that these grounds for rejection be withdrawn. However, should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect.

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